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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,186	07/08/2003	Arminas Ragauskas	01950-P0006D RJB	6458
24126	7590	05/23/2006	EXAMINER	
ST. ONGE STEWARD JOHNSTON & REENS, LLC 986 BEDFORD STREET STAMFORD, CT 06905-5619			APANIUS, MICHAEL	
			ART UNIT	PAPER NUMBER

3736

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/615,186	<b>Applicant(s)</b> RAGASKAS, ARMINAS	
	<b>Examiner</b> Michael Apanius	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-24 is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/17/2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. This office action is in response to the amendment filed 3/17/2006. The Examiner acknowledges the amendments to claims 1, 7 and 19; the amendment to the title, the amendments to the specification; and replacement drawings sheets 1-4, 6 and 7. Currently, claims 1-24 are pending.

#### ***Drawings***

2. The replacement drawings are accepted.

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Yost et al. (US 5,617,873).
5. In regards to claim 1, Yost et al. disclose a device (figure 2) for obtaining an indication of the intracranial pressure of a living body, comprising: a positional sensor (20) which is capable of determining an initial position of an elastic biological object when the intracranial pressure within the living body is zero and which is capable of determining a subsequent position of the elastic biological object when the intracranial

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pressure within the living body is unknown but greater than zero; a pressure generator (40) which applies an external pressure to the elastic biological object; and a comparator (30; column 6, line 22) which is capable of comparing the initial position with the subsequent position so as to identify the unknown intracranial pressure of the living body as that external pressure which causes the subsequent position to be equal to the initial position. Note that the positional sensor is an ultrasonic transducer which can be used to measure positions (column 6, lines 21-24). Furthermore, note that the comparator measures changes in the variations of skull size and therefore is capable of comparing positions.

6. In regards to claim 7, the device has a pressure indicator (60) for sensing the pressure applied by the pressure generator and indicating the pressure. The other elements of this claim are noted above in regards to claim 1.

7. In regards to claims 2 and 8, the elastic biological object is a skull bone (column 6, line 23).

8. In regards to claims 3 and 9, the pressure generator is an inflatable helmet (column 6, line 6).

9. Claims 1, 5-7, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Marchbanks (US 4,841,986).

10. In regards to claim 1, Yost et al. disclose a device (figure 3) for obtaining an indication of the intracranial pressure of a living body, comprising: a positional sensor (31; column 4, lines 51-58) which is capable of determining an initial position of an

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elastic biological object when the intracranial pressure within the living body is zero and which is capable of determining a subsequent position of the elastic biological object when the intracranial pressure within the living body is unknown but greater than zero; a pressure generator (20) which applies an external pressure to the elastic biological object; and a comparator (34; see also column 2, lines 43-52) which is capable of comparing the initial position with the subsequent position so as to identify the unknown intracranial pressure of the living body as that external pressure which causes the subsequent position to be equal to the initial position.

11. In regards to claim 7, the device is deemed to have a pressure indicator for sensing the pressure applied by the pressure generator and indicating the pressure. The pressure indicator is deemed necessary because the value of the applied pressure is needed to calculate middle ear pressure (column 5, lines 10-14). The other elements of this claim are noted above in regards to claim 1.

12. In regards to claims 5 and 11, the elastic biological object is a tympanic membrane (17).

13. In regards to claims 6 and 12, the pressure generator is a tube (20) adapted for insertion into an ear.

### ***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yost et al. (US 5,617,873) in view of Alban (US 4,505,278).

16. Yost et al. do not expressly disclose a piston and cylinder assembly mounted on a frame.

17. Alban teaches a piston (11B) and cylinder (10) assembly mounted on a frame (17) for the purpose of providing an inexpensive and accurate pressure generator (column 1, lines 39-43). The piston and cylinder taught by Alban is capable of applying pressure to a skull bone.

18. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a piston and cylinder assembly as taught by Alban in the device of Yost et al. in order to provide an inexpensive and accurate pressure generator.

#### ***Allowable Subject Matter***

19. Claims 13-24 are allowed.

20. The rejection raised in the previous office action of claims 19-24 under 35 U.S.C. 112, 2nd paragraph on the grounds that it is unclear when an "intracranial pressure is balanced with atmospheric pressure" is withdrawn. Upon further consideration, this limitation is deemed to be definite. The intracranial pressure is balanced with atmospheric pressure when no pressure differential exists between the intracranial pressure and atmospheric pressure.

***Response to Arguments***

21. Applicant's arguments filed 3/17/2006 have been fully considered but they are not persuasive.

22. In response to the applicant's assertion that the 102(b) rejection as being anticipated by Yost is improper because Yost was published after the filing date of the instant application, the Examiner notes that the prior art of record includes more than one Yost reference and that the 102(b) rejection is based upon US 5,617,873 which was issued on Apr. 8, 1997. Therefore, the rejection is proper.

23. In response to applicant's argument that neither Yost nor Marchbanks discloses using a pressure generator to move a biological object from a second position where this biological object is positioned when it is subject to positive intracranial pressure to a first position where the biological object is positioned when the biological object is subject to zero intracranial pressure (see remarks at page 10 of Applicant's Response), a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the pressure generators of Yost and Marchbank are both capable of moving a biological object from a second position to a first position where the biological object is positioned when the biological object is subject to zero intracranial pressure.

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**Conclusion**

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8:30am-5pm.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

26. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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